68/86



November 18, 1999



Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

In accordance with Section 403(r)(6), this is a letter of notification with regard to the marketing of EnteraHealth<sup>TM</sup> Intestinal Wellness, a dietary supplement containing NutraGammax<sup>TM</sup>, a protein complex with immunoglobulin concentrate from bovine serum.

Manufacturer: LG Laboratories

2325 North Loop Drive Ames, Iowa 50010

"Statements Made in Labeling."

- "... actively support and maintain gastrointestinal health"
- "... provides intestinal wellness support ..."
- "... to help maintain gastrointestinal balance and support normal nutrient absorption"

"NutraGammax™ promotes normal gastrointestinal health by:

- Promoting Intestinal Function
- Increasing Intestinal Absorptive Surface Area
- Optimizing the Utilization of Nutrients . . . "

"... to promote intestinal health in humans"

"... provides GI and immune support while optimizing the uptake of nutrients"

"... to help ... promote and maintain intestinal health function"

- Promote GI balance
- Support normal digestive absorption for stable GI function
- Provide a supplemental source of antibodies for immune support

"To the best of my knowledge, the information contained in this notice is complete and accurate, and LG Laboratories has substantiation that the statements are truthful and not misleading."

Mel Vanden Berg

V.P. Quality Assurance

MVB/jsh